



July 20, 2017

## **Intra-Cellular Therapies Presents at the 2017 International College of Neuro-Psychopharmacology (CINP) Thematic Meeting on Treatment-Resistant Depression**

NEW YORK, July 20, 2017 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced it had given both oral (symposium) and poster presentations related to lumateperone at the 2017 Collegium Internationale Neuro-Psychopharmacologicum (CINP) Thematic Meeting: Treatment Resistant Depression held in Prague, July 20-22. The presentations were:

Symposium presentation entitled "*ITI-007 — a novel antipsychotic drug with potent SERT inhibitory action and D1-dependent indirect modulation of glutamate — Clinical profile.*" presented Thursday, July 20, 2017 during Symposium 2 — Atypical antipsychotic augmentation in TRD: an update.

Poster Presentation P026 entitled "*Lumateperone Uniquely Enhances Glutamatergic Neurotransmission through activation of both NMDA and AMPA channels via a dopamine D1 receptor-dependent mechanism: Implications for Treatment of Mood Disorders.*" presented on Thursday, June 20 and Friday, July 21, 2017 during the Poster Sessions.

Poster Presentation P028 entitled: "*Unique Pharmacology and Clinical Evidence Supporting the Antidepressant Therapeutic Potential of Lumateperone*" presented on Thursday, June 20 and Friday, July 21, 2017 during the Poster Sessions.

In presentations at the CINP meeting, the Company presented an update on the late stage clinical program in schizophrenia with its most advanced agent lumateperone. In addition to summarizing the two, positive, large efficacy studies conducted to date, more recently generated nonclinical data further characterizing the unique pharmacology of this first-in-class investigational agent were summarized supporting the unique mechanism of action of lumateperone at the dopamine D2 receptor, as a pre-synaptic D2 partial agonist and a post-synaptic D2 antagonist. This novel finding is believed to form the basis of efficient modulation of dopamine, providing antipsychotic efficacy at relatively low striatal D2 receptor occupancy without the motoric disturbances associated with many current therapies. Further, the Company shared recent data, demonstrating that lumateperone, as a standalone agent, indirectly enhances glutamatergic neurotransmission through both AMPA and NMDA channels in the prefrontal cortex, mechanisms thought to predict potent and rapid antidepressant effects. This finding had not previously been observed with an antipsychotic agent in the absence of antidepressant augmentation. These effects on glutamate neurotransmission are dependent on the ability of lumateperone to increase D1 receptor activity and inhibit SERT activity, unique amongst current antipsychotic drugs. Additionally, the Company presented data demonstrating that lumateperone, consistent with a rapid acting antidepressant effect, increases protein phosphorylation of key proteins in the mTOR pathway. These findings, in addition to the potent SERT activity previously described with lumateperone, suggest the potential for lumateperone to exhibit potent and rapid antidepressant effects in patients suffering from a range of mood disorders. With over 1500 individuals exposed to date in clinical trials, lumateperone has been well-tolerated with a safety profile similar to placebo. In addition to schizophrenia, lumateperone is in Phase III clinical development as a treatment for bipolar depression and agitation of dementia, including Alzheimer's disease.

### **About Intra-Cellular Therapies**

Intra-Cellular Therapies is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative diseases and diseases of the elderly, including Parkinson's and Alzheimer's disease. The Company is developing its lead drug candidate, lumateperone (also known as ITI-007), for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. Lumateperone, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer's disease. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders.

### **Forward-Looking Statements**

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, our clinical and non-clinical development plans; the progress, timing and results

of our clinical trials and preclinical studies; our beliefs about the extent to which the results of our clinical trials and preclinical studies to date support new drug application filings for lumateperone; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of our drug product candidates; and development efforts and plans under the caption "About Intra-Cellular Therapies." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include but are not limited to the following: our current and planned clinical trials, other studies for lumateperone, and our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

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